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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,325	03/25/2004	Lawrence R. McGee	T99-008-3/US	7972
30174 7590 12/18/2006 AMGEN INC. 1120 VETERANS BOULEVARD SOUTH SAN FRANCISCO, CA 94080			EXAMINER SEAMAN, D MARGARET M	
			ART UNIT	PAPER NUMBER
			1625	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/18/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/810,325

Applicant(s)

MCGEE ET AL.

Examiner

D. Margaret Seaman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,15-20 and 55-86 is/are pending in the application.
- 4a) Of the above claim(s) 73-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,15-20 and 55-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application was filed 3/25/2004 and is a CON of 10/209205 (7/30/2002, US Patent #6770648) which is a CON of 09/606433 (6/28/2000, US Patent #7041691) which claims benefit of 60/141672 (filed 6/30/1999). Claims 1-8, 15-20 and 55-86 are pending. Claims 73-86 remain withdrawn from consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-8, 15-20 and 55-72 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for X being -S(O)_k-, -O-, -C(O)- and CH₂, does not reasonably provide enablement for X being -C₂₋₆ alkylene, alkyleneoxy, alkylenamino, alkylene-S(O)_k-, -N(R₁₁)C(O)-, -NR₁₁- and a single bond. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to modify the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue".

These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the

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state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

- 1) The breadth of the claims,
- 2) The nature of the invention,
- 3) The state of the prior art,
- 4) The level of one of ordinary skill,
- 5) The level of predictability in the art,
- 6) The amount of direction provided by the inventor,
- 7) The existence of working examples,
- 8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The nature of the invention: The nature of the invention is compounds that could be useful to treat PPAR gamma modulated conditions using a compound that is of formula of claim 1.

The state of the prior art: The state of the prior art is that it involves similar and dissimilar compounds that are alleged to modulate PPAR gamma receptors. Screening in vitro and in vivo is necessary to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease).

There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

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The predictability in the art: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In *re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the closest two compounds tested are 233 and 365, their main difference being X is NH for 233 and X being O for 365 and their activities were measured on page 200 with the activity of 233 as <10% and 365 being >20%, the highest different tested. These compounds compare to the instantly claimed compounds as the Ar1 being benzothiazole as compared to the instant phenyl or naphthyl. Due to this, it is not seen where the instantly claimed invention has any predictability in the art. The instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to the activity of the instant compounds, if the benzothiazole compounds are this unpredictable, then the instantly claimed compounds are also unpredictable. Hence, in the absence of a showing of predictability between all various X moieties, one of ordinary skill in the art is unable to fully predict possible results from the instant compounds' X being other than the instantly shown -S(O)_k-, -O-, -C(O)- and CH₂.

The presence or absence of working examples: As stated above, there are no working examples that compare the activity of the instantly claimed compounds wherein Ar1 being phenyl or naphthyl and R2 being aryl. The closest compounds tested are 233 and 365 (wherein Ar1 is benzothiazole and R2 being phenyl) which show wide differences in activity for a minor change in X (from -O- to -NH-).

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The amount of direction or guidance present: The guidance present in the specification is that of the compounds that all compounds that fall within the large markush shown in the specification work to treat diabetes or other PPARgamma modulated diseases. As shown above, very similar compounds have been shown to have wide differences in activity levels

The breadth of the claims: The claims are drawn to millions of compounds wherein there are three aromatic rings connected through some type of divalent linkage

The quantity of experimentation needed: The quantity of experimentation needed is undue. One skilled in the art would need to determine what compounds of the many encompassed by the instant claim 1 should be made and then tested for PPAR gamma activity.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of claim 1 for the treatment of any disease. As a result necessitating one of ordinary skill to perform an exhaustive search for which diseases can be treated by which compound of claim 1 in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, one of ordinary skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compounds of the instant claims, with no assurance of success.

This rejection can be overcome by deleting the claims.

Applicants argue in paper dated 10/12/2006 that the claims are not overbroad. This is not one of the considerations of a scope of enablement rejection. Further, applicants argue that the entire scope of the claimed compounds would be routine. However, by the above considerations, it is not seen where only minor experimentation would be required to complete the scope of the instantly claimed compounds. Applicants also argue that numerous working examples are given in the instant specification. However, there are more than three hundred examples of compounds in the specification. Very few of them fall within the instant genus. Further, none of them have been tested for activity as compared to each other of the same instant genus.

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1-8, 15-20 and 55-72 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6602827. Although the conflicting claims are not identical, they are not patentably distinct from each other because the markush disclosed in the patent's opening pages contains the central phenyl ring being optionally substituted and many examples (such as examples 48 and 49) contain the substituted phenyl ring. There is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application that matured into a patent. The difference between the instant claim and the claims of the patent is that the patent claims an unsubstituted phenyl ring as compared to the instantly claimed substituted phenyl ring.

Claim Rejections - 35 USC § 102

5. The rejection of claims under 35 USC § 102(b) is withdrawn.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 571-272-0694. The examiner can normally be reached on 730am-4pm, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. Margaret Seaman
Primary Examiner
Art Unit 1625

dms